Better Training for Safer Food
Initiative

Towards a Sustainable Use of Plant Protection Products: "Safe Use - Identification of hazards and risks to humans"

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Consumers, Health And Food Executive Agency

European Commission

Presentation outline

A. Hazards and Risks:

a.1 Definitions
a.2 Hazard Identification & Characterisation

B. Risk assessment:

b.1 R.A.: Consumer & Operator
b.2 Routes of exposure
b.3 Operator exposure estimation tools

C. Pesticide Label and Safety Data Sheet

c.1 Interpretation of label and SDS in relation to classification
c.2 Interpretation of label in relation to safety precautions & PPE recommendations
c.3 Interpretation of label in relation to first aid measures

A. Hazards and Risks:

a.1 Definitions

RISK = $f(x)$ Hazard (Toxicity) x Exposure

the capacity of a pesticide to cause injury

The potential for injury to take place

The amount of a pesticide contacting or entering the body

a.2 Hazard Identification & Characterization

«The dose makes the poison»

…. applies in most of the cases for pesticides also.

Paracelsus, 1493-1541,
Swiss alchemist & doctor

a.2 Hazard Identification & characterization

Studies of pesticide effects on mammals

PURPOSE

Prediction of effects in humans

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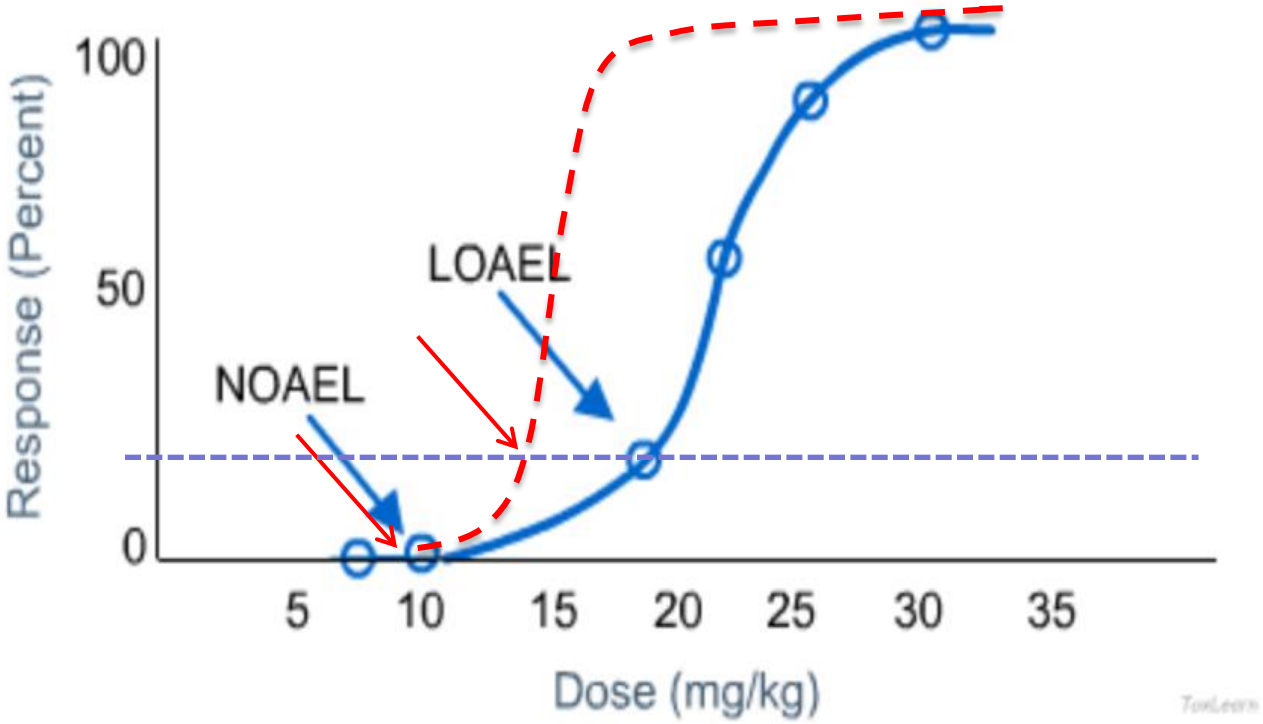
The dose – response curve



NOAEL: Non Adverse Effect Level
LOAEL: Lowest Adverse Effect Level

Types of studies

Plant Protection Product

- Acute Oral, Dermal, Inhalation
- Skin & Eye Irritation
- Skin Sensitization
- Supplementary studies
  (e.g. combinations of PPPs)
- Exposure data
  - Operator
  - Bystander & Resident
  - Worker
- Dermal absorption
- Toxicological data relating to formulants

Active & other substances

- Absorption, Distribution, Metabolism, Excretion
- Acute Oral, Dermal, Inhalation
- Skin & Eye Irritation
- Skin Sensitization & Phototoxicity
- Short term toxicity
- Genotoxicity
- Long term toxicity & Carcinogenicity
- Reproductive toxicity

[Multi-generation – Developmental]

- Neurotoxicity
- Other toxicological studies [Toxicity studies of metabolites or supplementary studies on the active substance, e.g. mechanistic studies]
- Medical data

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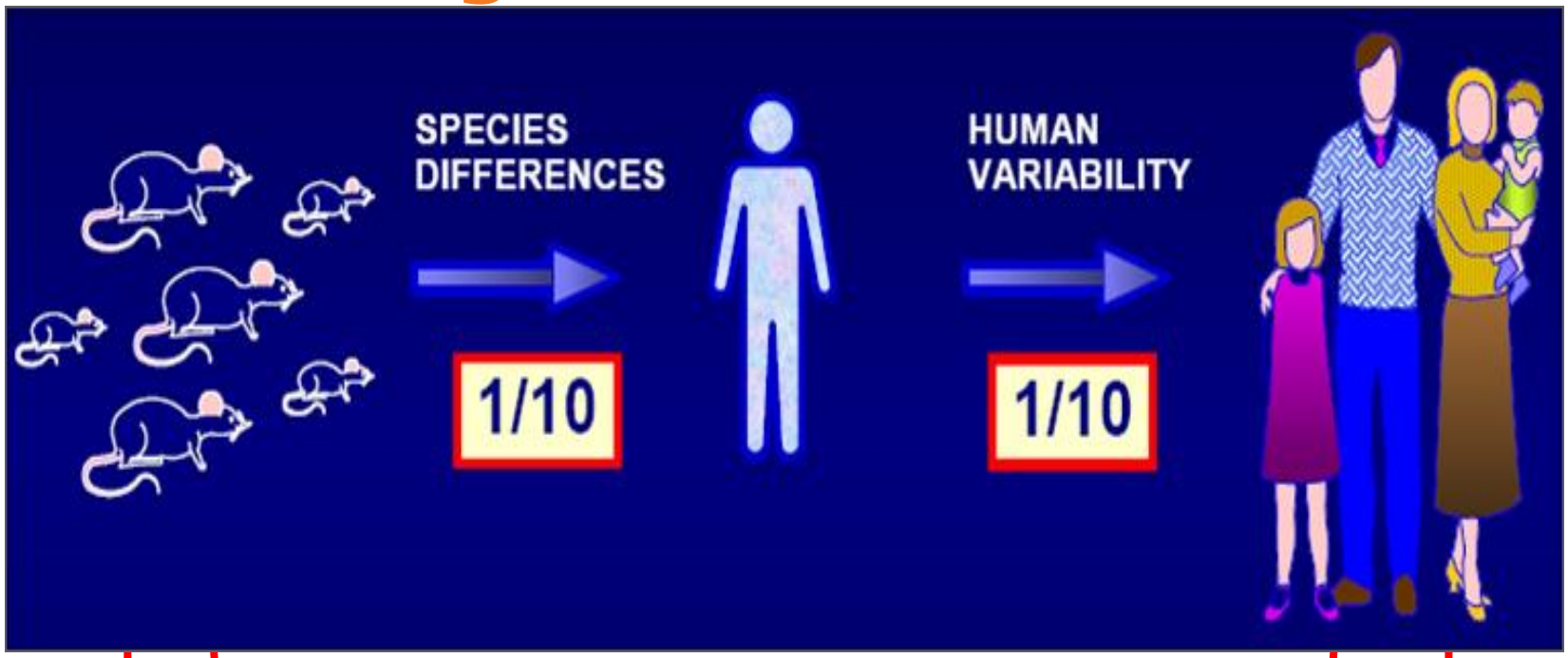
Setting of threshold values



NOAEL ÷ **Assessment Factors (100)** = **Toxicological thresholds: [ADI, AOEL, ARfD, AAOEL]**

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Toxicological Thresholds

ADI: Acceptable Daily Intake – Threshold for lifespan dietary exposure.

ARfD: Acute Reference Dose – Threshold set for compounds that pose risk for effects following single or short term dietary exposure, e.g. acute or subacute effects.

AOEL*: Acceptable Operator Exposure Levels – Threshold for repeated non dietary exposure.

AAOEL: Acute Acceptable Operator Exposure Levels –** Threshold for compounds that pose risk for effects following single or short term non dietary exposure (development of GD for AAOEL setting, priority for EFSA and the Commission).

*** In EFSA calculator renamed to: Reference value non acutely toxic active substance (RVNAS)**

**** In EFSA calculator renamed to: Reference value acutely toxic active substance (RVAAS)**

Plant Protection Product database

http://ec.europa.eu/sanco_pesticides/public/?event=homepage&language=EN

B. Risk Assessment

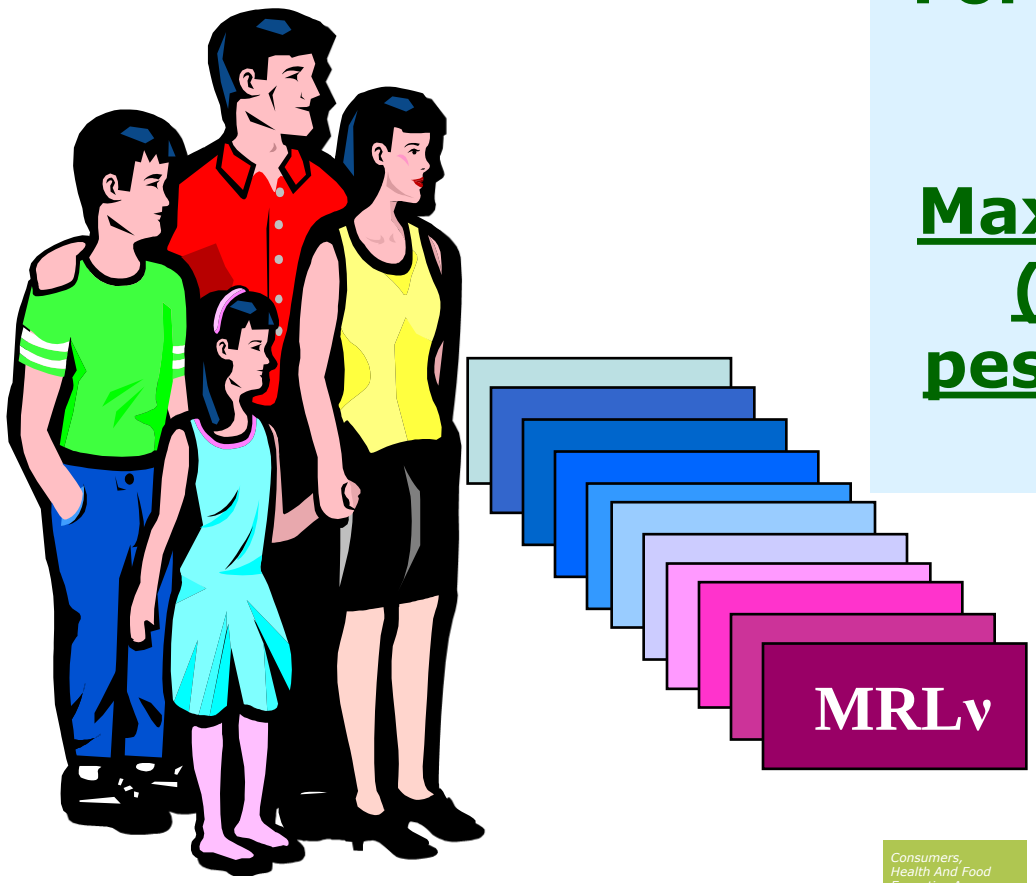
RISK

Acceptable or

Not acceptable

?

b.1 Consumer Risk Assessment



For consumer protection:
Compare the ADI to the sum of Maximum Residue Limits (MRLs) of a specific pesticide in the different foods consumed

$$\sum MRL \leq ADI$$

b.1 Operator, Worker, Bystander, Resident Risk Assessment

For the protection of the operator, worker, bystander and resident: <u>Compare the AOEL to the Exposure</u>

$$E < AOEL$$

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b.2 Routes of exposure to pesticides and their entrance in the organism

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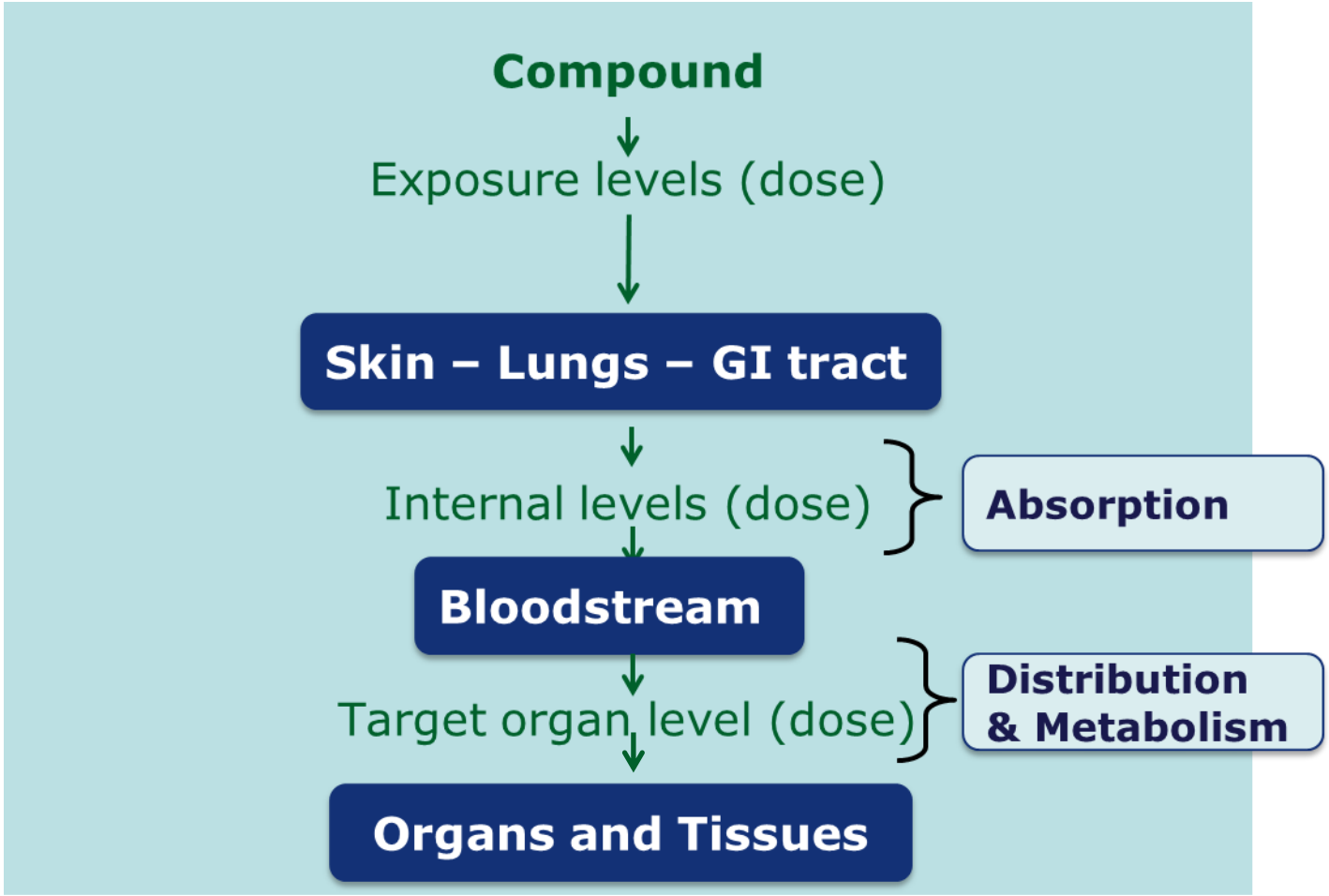
Exposure *v.s.* internal dose



SKIN: Dermal route of exposure*

97% of all body exposure during application is by skin contact.

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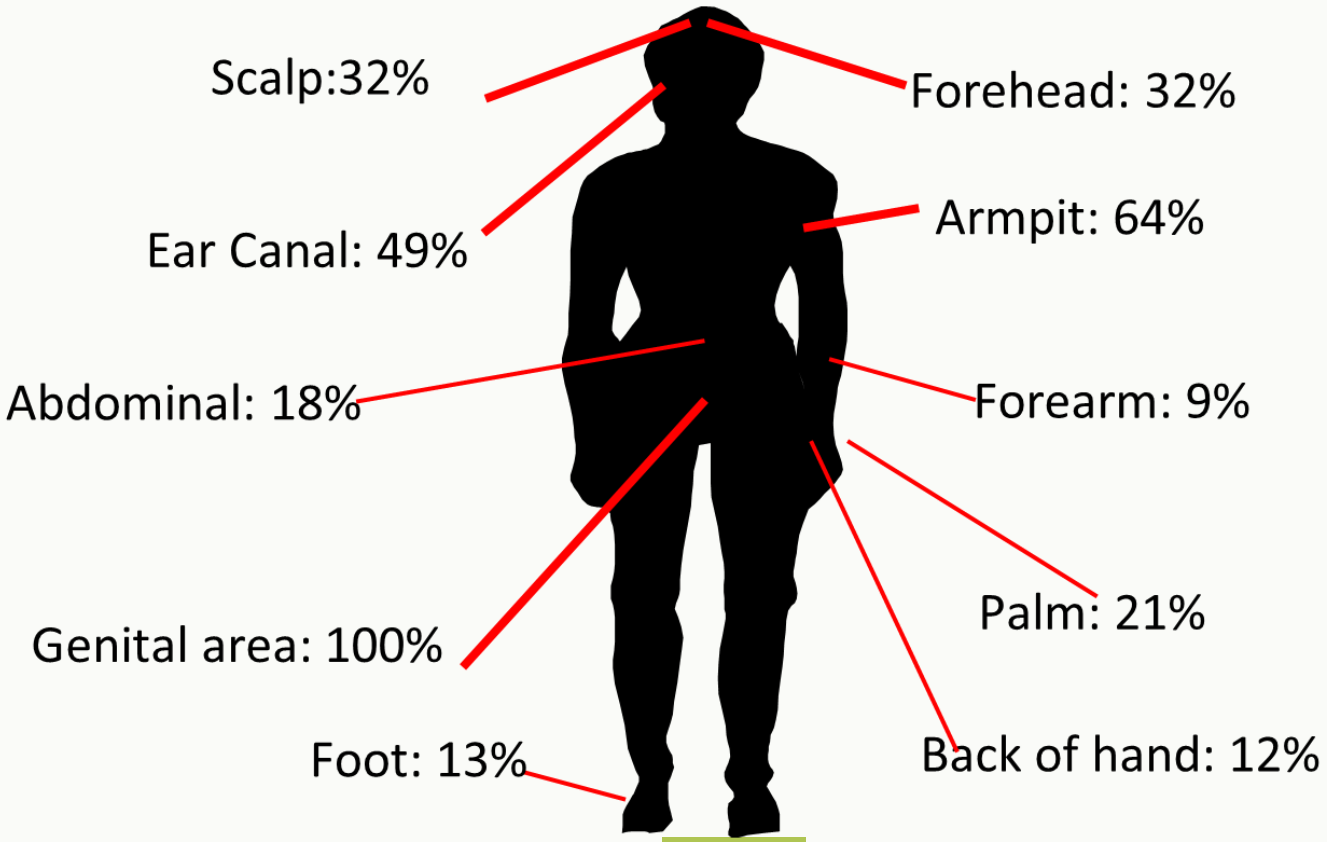
Different parts of the body vary in their ability to absorb pesticides*

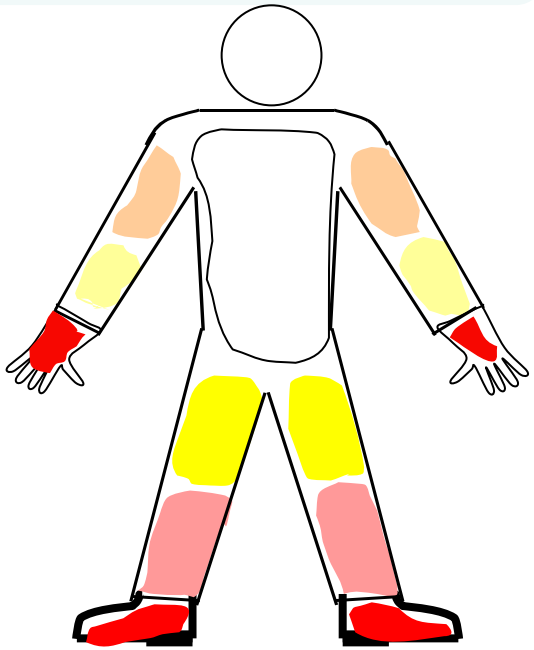


Distribution of spray solution in the different body parts

Measurements after herbicide application

% total exposure

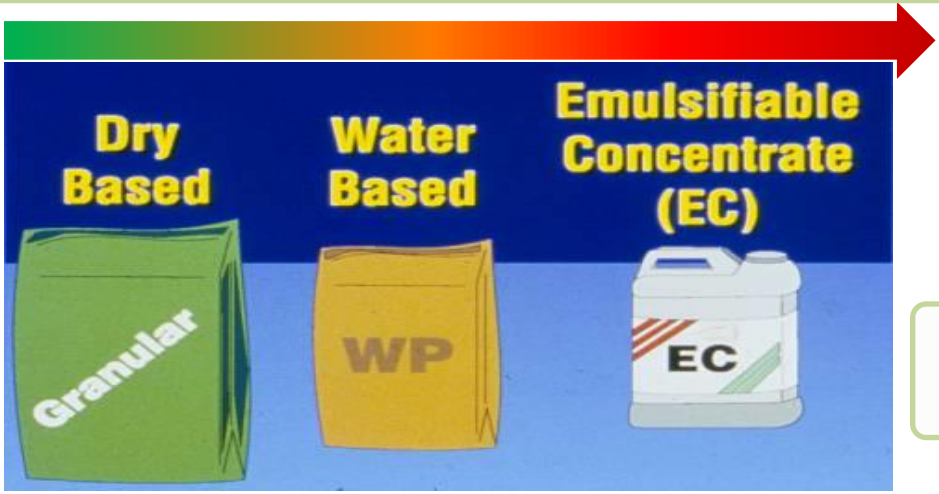
- 1
- 4
- 8
- 15
- 30
- 45



Factors that influence the dermal absorption*:

- Different anatomical sites…
- Warm and moist areas with increased blood vessels
- Skin condition such as cuts, abrasions and rashes
- Type of pesticide formulation

Lower absorption

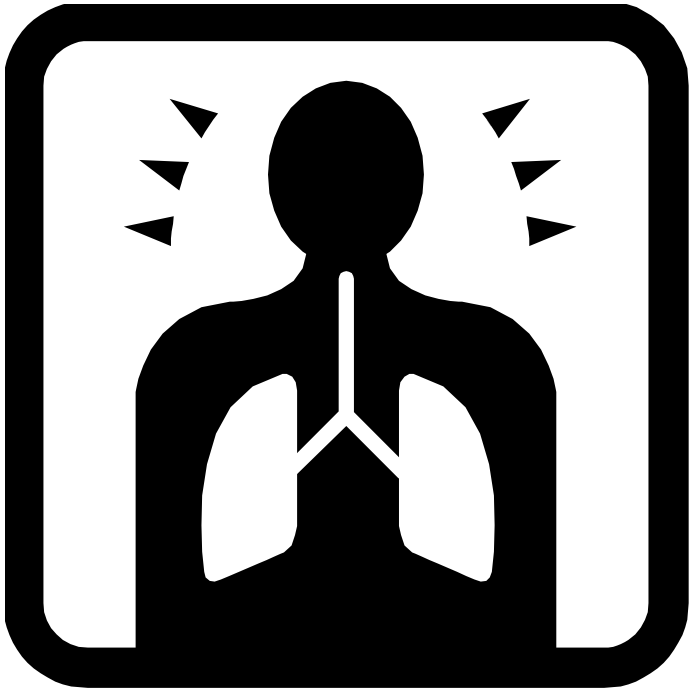


Higher absorption

LUNGS: Route of entry *via* inhalation*

Exposure *via* Inhalation can occur:

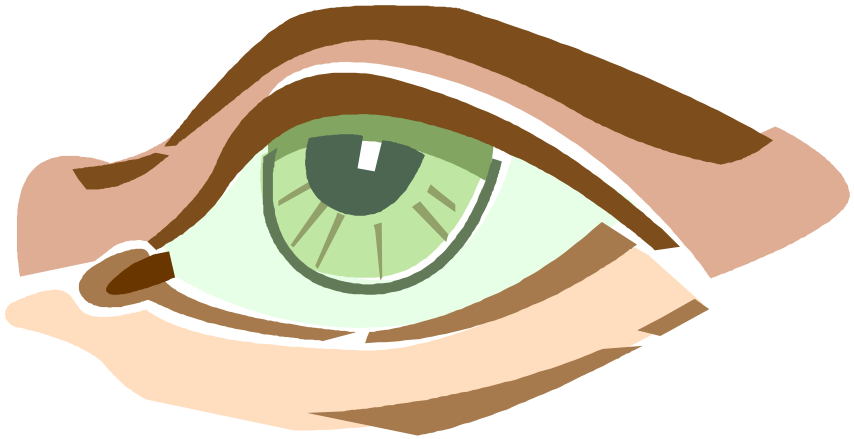
- When using wettable powders, dusts, gases, vapors and sprays
- While mixing and loading pesticides
- During application



EYES* :

Entry *via* mucous membranes and microcapillaries

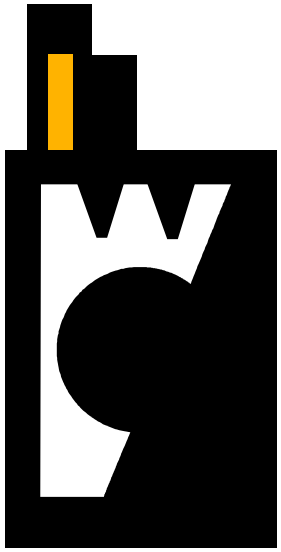
- Eyes are able to absorb surprisingly large amounts.
- Local effects can be produced, from irritation to irreversible injuries.

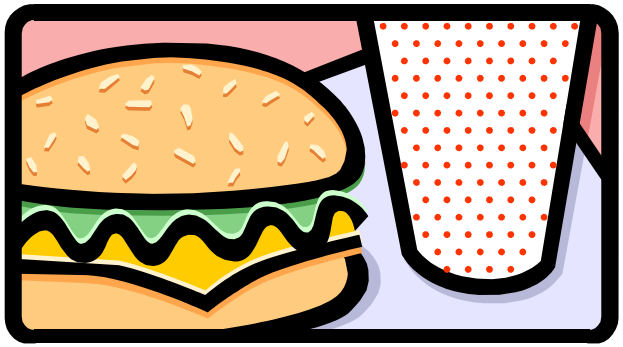


MOUTH: oral route of exposure*

WASH YOUR HANDS!!

Before eating, drinking, smoking or going to the bathroom, at breaks and before using your mobile phone.





Routes of exposure to pesticides and their entrance in the organism

1. SKIN: dermal exposure (COVERALL & GLOVES)
2. RESPIRATORY TRACT: exposure by inhalation (MASK)
3. MOUTH: exposure by swallowing (MASK, FACE SHIELD & BASIC PRECAUTIONS)
4. EYES: via mucosal membranes (PROTECTIVE GOGGLES & FACE SHIELD)

REDUCTION OF THE AMOUNT THAT ENTERS INTO THE SYSTEMIC CIRCULATION:

Thorough washing of the whole body with water & soap after the pesticide application (reduction of exposure >60%).

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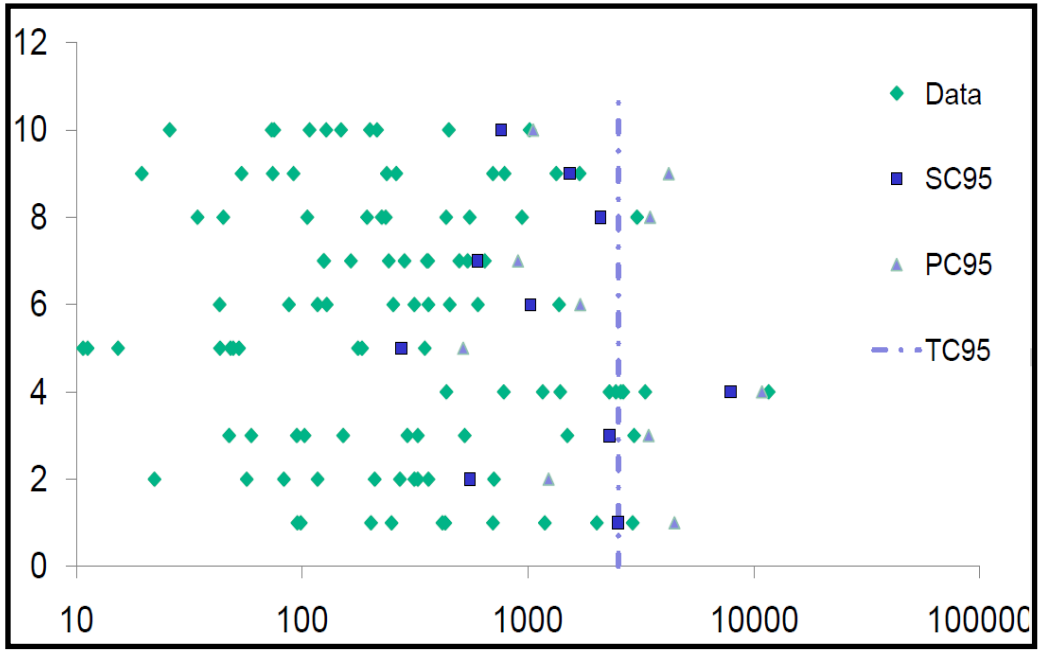
b.3 Operator exposure estimation tools

C. Pesticide Label

c.1 Product labelling & classification
c.2 Interpretation of label in relation to safety precautions & PPE recommendations
c.3 Product safety data sheet and First aid measures

b.3 Operator exposure estimation tools

The operator exposure levels to pesticides can be estimated either with mathematical models of measured from field studies.



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The currently used OPEX estimation models

German Model
outdoor

UK POEM
outdoor

EUROPOEM data (outdoor & indoor)

Dutch Greenhouse Model

ECPA Southern European Greenhouse Model

Seed TROPEX (seed treatment & loading calibration bagging, sowing of treated seeds)

Higher tier data: Exposure measurements from relevant studies (type of PPP's & application pattern, mixing loading)

New exposure estimation tool, Operator, Worker, Bystander & Resident

EFSA Calculator

EFSA Guidance, 2014

- *<u>Background document</u>:*
  EFSA, 2008b. Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents, EFSA AGREEMENT NUMBER: EFSA/PPR/2007/01, FINAL REPORT, 28 NOVEMBER 2008.

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EFSA JOURNAL

Available online:
http://www.efsa.europa.eu/en/efsajournal/pub/3874.htm

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products

EFSA Journal 2014;12(10):3874[55 pp.]. doi:10.2903/j.efsa.2014.3874

European Food Safety Authority
Acknowledgment
Contact

Type: Guidance of EFSA
On request from: European Commission
Question number: EFSA-Q-2011-01062
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Last updated: 24 April 2015. This version replaces the previous one/s.
Affiliation: European Food Safety Authority (EFSA), Parma, Italy

Article (1.0 Mb) ← Send Print Cite

Excel calculator (0.1 Mb) ←

Abstract

Regulation (EC) No 1107/2009 ensures that the residues of plant protection products (PPPs), consequent to application consistent with good plant protection practice and having regard to realistic conditions of use, shall not have any harmful effects

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C. Pesticide Label and Product safety Data Sheet

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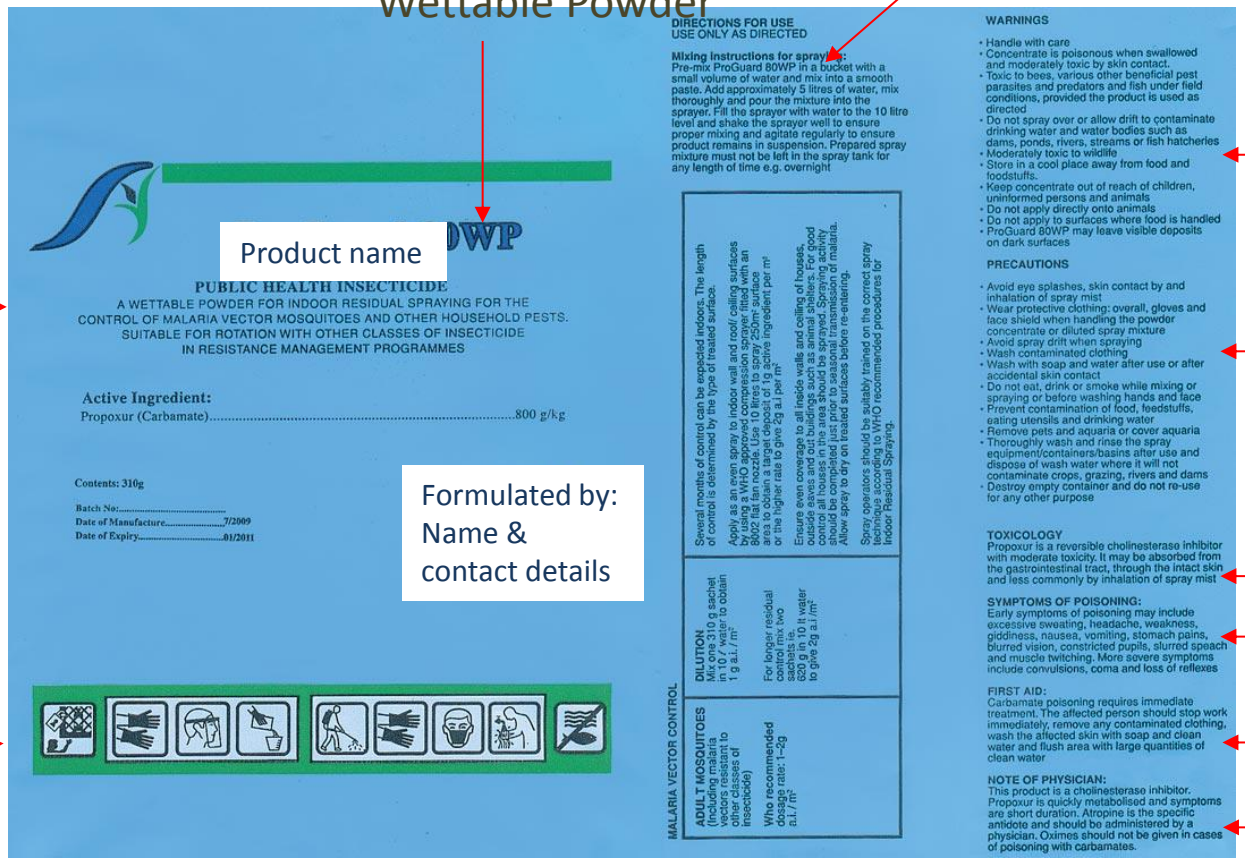
Example of a PPP label

Product type: Wettable Powder

Directions for use



Type of PPP

Pictograms

Warnings

Precautions

Toxicology

Symptoms of poisoning

First aid

Note of physician

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The Product Safety Data Sheet (SDS)

L 132/8 EN Official Journal of the European Union 29.5.2015

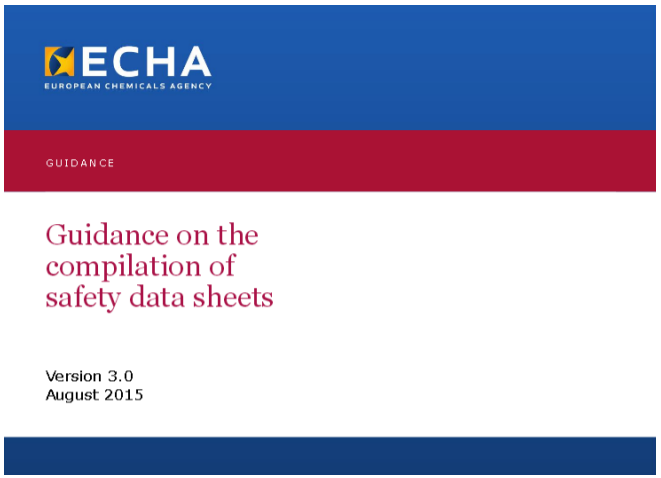
COMMISSION REGULATION (EU) 2015/830

of 28 May 2015

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Guidance on the compilation of safety data sheets according to the requirements in place from 1 June 2015

http://echa.europa.eu/documents/10162/13643/sds_en.pdf



What is a PRODUCT SAFETY DATA SHEET

2.1 Definition of a Safety Data Sheet (an SDS)

- An SDS is aimed to provide information about a substance or mixture for use in workplace.
- It is used as a source of information about hazards, including environmental hazards, and to obtain advice on safety precautions.
- To be used: at workplace (e.g. professional use of pesticides), consumers, for transport of dangerous goods, in emergency situations (including poison centers)

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c.1
Interpretation of label and SDS in relation to product classification

The legal framework for Hazard Classification

…the new CLP (GHS) system

REGULATION (EC) No 1272/2008 of The European Parliament and of the Council *of the 16th December 2008 on Classification, Labelling and Packaging (CLP Regulation) of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1097/2006*

With this Regulation (CLP) the internationally agreed criteria in the Globally Harmonized System are incorporated into Community Law

Entry into force

Substances: 1 December 2010, Mixtures: 1 June 2015

Essential elements on a PPP Label

Hazard pictograms										
	flammable	explosive	flammable & explosive	fatal toxic	Allergen CMR STOT	gas under pressure	Corrosive to metals skin burns eye dmg	harmful irritant allergen	allergen CMR STOT	
Signal words	Danger					Warning				
Hazard statements	H200 - H290: hazard statements for physical hazards H300 - H373: hazard statements for health hazards H400 - H413: hazard statements for environmental hazards									
Precautionary statements	P101 – P103: precautionary statements – general P201 – P285: precautionary statements – prevention P301 – P391: precautionary statements – response P401 – P422: precautionary statements – storage P501 : precautionary statements – disposal									

c.2
Interpretation of label and SDS in relation to safety precautions and PPE recommendations

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What are the determinants for PPE recommendations?

a

The hazardous properties of active ingredient(s) and co-formulants (C,M,R, EDs)

b

Risk for the operator & worker

PPE recommendations on Pesticide Label

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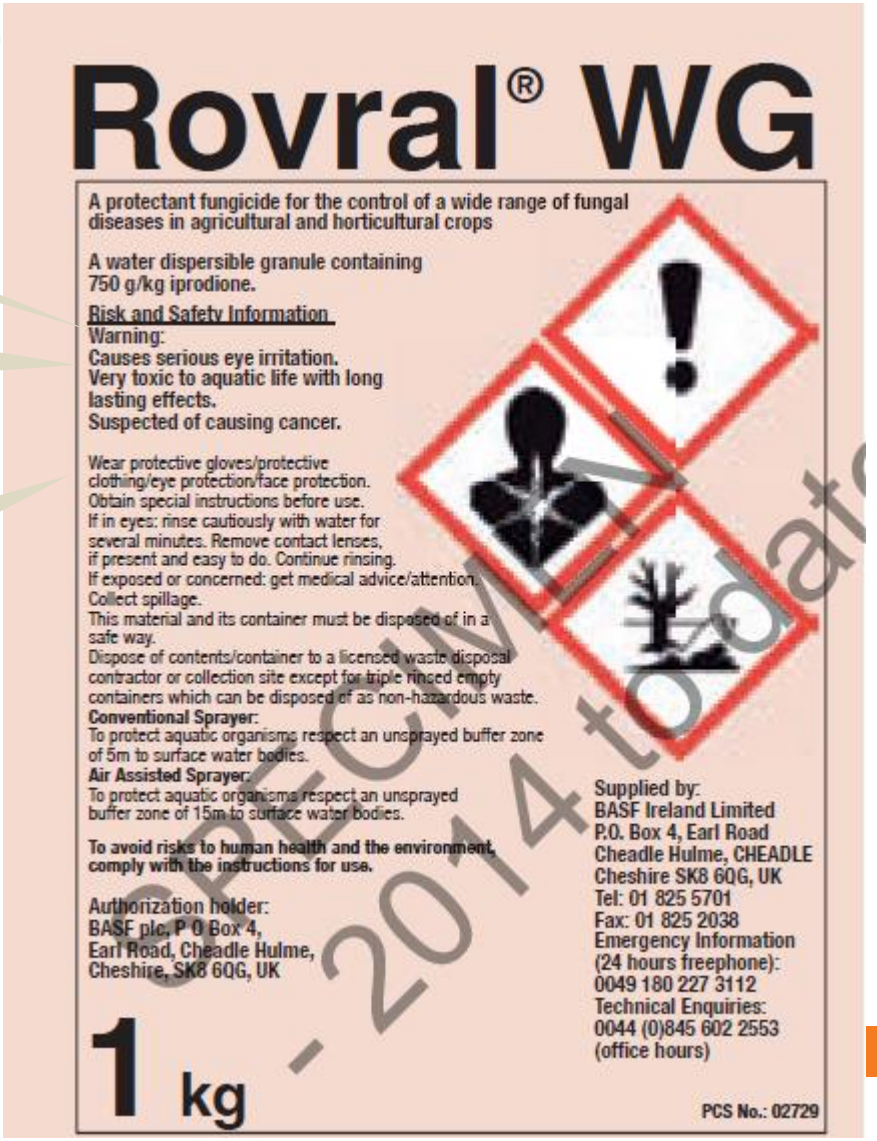
Signal word:
Warning

Hazard class (health effects):
Causes serious eye irritation
Suspected of causing cancer

PPE (statement of prevention):
Wear protective gloves / protective clothing / eye protection / face protection



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No Hazard Classification

PPE:
Wear suitable gloves

PEEL HERE FOR DIRECTIONS FOR USE

FOR USE ONLY AS A NON-SELECTIVE HERBICIDE IN NON-CROP AREAS.

SAFETY INFORMATION

KEEP OUT OF REACH OF CHILDREN.

WEAR SUITABLE GLOVES.

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.

IF SWALLOWED, SEEK MEDICAL ADVICE IMMEDIATELY AND SHOW THIS CONTAINER OR LABEL.

THIS MATERIAL AND ITS CONTAINER MUST BE DISPOSED OF IN A SAFE WAY.

To avoid risks to man and the environment, comply with the instructions for use.

PCS Number: 02314

Marketed in Ireland by:
MONSANTO IRELAND LIMITED
Unit C2, Dunshaughlin Business Park
Dunshaughlin, County Meath
Tel.: (01) 825 0555 / 825 0574, Fax: (01) 825 0570

Authorisation holder:
MONSANTO UK LIMITED
The Maris Centre, 45 Hauxton Road
Trumpington, Cambridge, CB2 9LQ, UK

In case of emergency day or night, telephone Chemical Emergency Centre: 00 44 1865 407333

READ CAREFULLY THE RECOMMENDATIONS FOR USE ATTACHED TO THIS CONTAINER

All users must ensure that they have read this leaflet and follow its advice before using the product.

Protect from frost. **Imported**

PPE recommendations on a Pesticide Label

Code	Prevention precautionary statement	Hazard class	Hazard category
P280	Wear protective gloves/protective/clothing/ eye protection/face protection.	Acute toxicity - dermal	1, 2, 3, 4
		Skin corrosion	1A, 1B, 1C
		Skin / eye irritation	2
		Skin sensitization / serious eye damage/irritation	1
P284	Wear respiratory protection	Acute toxicity — inhalation	1, 2
P285	In case of inadequate ventilation wear respiratory protection.	Respiratory sensitisation	1

The importance of pesticide label -Application rate & PPE

Recommended application rate:7.5 L product/ha (1.125 kg a.i./ha), Spray volume: 500 L/ha, Treated area: 5 ha/day - field crop; tractor mounted

Estimation of operator exposure (acc. to the German model)

Active substance (a.s.)	glufosinate ammonium	
Product	BASTA 15 SL	
Intended use(s)	olive trees	
	Field Crops, Tractor Mounted (FCTM)	
Type of preparation	Liquid	
Application rate (AR)	1.125	kg a.s./ha
Treated area per day (A)	5	ha/d
Systemic AOEL	0.0021	mg/kg bw/d
Dermal absorption (DA)	16	% for mixing/loading (m/l)
	14	% for application (appl.)
Inhalation absorption (IA)	100	%
Body weight (BW)	70	kg

No PPE: exposure levels, exceeded AOEL by **2600%**

With PPE: 98% AOEL

Application rate + 10%

No PPE: exposure levels exceeded AOEL by **2825%**

With PPE: 108% AOEL

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c.3
Interpretation of label and SDS in relation to first aid measures

1st aid measures & precautionary statements

- Annex IV to Regulation (EC) 1272/2008: list of precautionary statements

  P101 – P103: precautionary statements – general

  P201 – P285: precautionary statements – prevention

  P301 – P391: precautionary statements – response *{considered under first aid measures due to their purpose}*

  P401 – P422: precautionary statements – storage

  P501: precautionary statements – disposal

First-aid measures: Regulation (EC) 1272/2008

(Table 6.2 - Precautionary statements — Response)

Code	Response precautionary statement	Hazard class	Hazard category
P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.	Acute toxicity — oral	1, 2, 3
		Aspiration hazard	1
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.	Acute toxicity — oral	4
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.	Skin corrosion	1A, 1B, 1C
P302 + P334	IF ON SKIN: Immerse in cool water/wrap in wet bandages.	Pyrophoric liquids	1
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.	Acute toxicity — dermal	1, 2
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.	**Acute toxicity — dermal**	3, 4
		Skin irritation	2
		Skin sensitisation	1, 1A, 1B
P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/ shower.	Flammable liquids	1, 2, 3
		Skin corrosion	1A, 1B, 1C

First-aid measures (2)

Code	Response precautionary statement	Hazard class	Hazard category
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.	Acute toxicity — inhalation	1, 2, 3, 4
		Skin corrosion	1A, 1B, 1C
		Specific target organ toxicity — single exposure; respiratory tract irritation	3
		Specific target organ toxicity — single exposure; narcosis	3
P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.	**Respiratory sensitisation**	
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	Skin corrosion	1A, 1B, 1C
		Serious eye damage/eye irritation	1
		Eye irritation	2
P306 + P360	IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.	Oxidising liquids	1
		Oxidising solids	1

First-aid measures (3)

Code	Response precautionary statement	Hazard class	Hazard category
P307 + P311	IF exposed: Call a POISON CENTER or doctor/ physician.	Specific target organ toxicity — single exposure	1
P308 + P313	IF exposed or concerned: Get medical advice/ attention.	Germ cell mutagenicity	1A, 1B, 2
		Carcinogenicity	1A, 1B, 2
		Reproductive toxicity	1A, 1B, 2
		Reproductive toxicity — effects on or via lactation	Additional category
P309 + P311	IF exposed or if you feel unwell: Call a POISON CENTER or doctor/ physician.	**Specific target organ toxicity — single exposure**	2
P332 + P313	If skin irritation occurs: Get medical advice/attention.	Skin irritation	2
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.	Skin sensitisation	1, 1A, 1B
P335 + P334	Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages.	Pyrophoric solids	1
		Substances and mixtures which, in contact with water, emit flammable gases	1, 2

First-aid measures (4)

Code	Response precautionary statement	Hazard class	Hazard category
P337 + P313	If eye irritation persists: Get medical advice/attention.	**Eye irritation**	2
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/ physician.	Respiratory sensitisation	1, 1A, 1B
P370 + P376	In case of fire: Stop leak if safe to do so.	Oxidizing gases	1
P370 + P378	In case of fire: Use … for extinction. *[… Manufacturer/supplier to specify appropriate media. — if water increases risk.]*	Flammable liquids	1, 2, 3
		Flammable solids	1, 2
		Self-reactive substances and mixtures	A, B, C, D, E, F
		Pyrophoric liquids	1
		Pyrophoric solids	1
		Substances and mixtures which, in contact with water, emit flammable gases	1, 2, 3
		Oxidising liquids	1, 2, 3
		Oxidising solids	1, 2, 3

First-aid measures (5)

Code	Response precautionary statement	Hazard class	Hazard category
P370 + P380	In case of fire: Evacuate area.	**Explosives**	Divisions 1.1, 1.2, 1.3, 1.4, 1.5
P370 + P380 + P375	In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.	Self-reactive substances and mixtures	Types A, B
P371 + P380 + P375	In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.	Oxidising liquids	1
		Oxidising solids	1

Further reading: The EU Legislation

DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

Reg. (EC) 283/2013: COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Reg. (EC) 284/2013 : COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Dir. 1999/45/ECDIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Dir. 67/548/EEC: COUNCIL DIRECTIVE of 27 Tune 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC) This Directive has been amended several times. Regulation (EC) No 1272/2008 has made remarkable modifications, and it shall repeal directive 67/548/EEC from 1 June 2015 by introducing the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Further reading: The EU Legislation

Reg. (EC) 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Reg. (EC) 547/2011 COMMISSION REGULATION (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

Reg. (EC) 1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

Calculation models

- http://www.bvl.bund.de/EN/04_PlantProtectionProducts/11_Applicants/02_AuthorisationProcedure/06_Toxicology/PlantProtectionProducts_toxicol_node.html
- http://www.efsa.europa.eu/en/efsajournal/pub/3874.htm

*Reference: Carol Ramsay, Pesticide Education Specialist, Washington State University

Thank you for your attention!

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Better Training for Safer Food

BTSF

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Consumers, Health and Food Executive Agency

DRB A3/042

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