

# **Methylene Chloride: Risk Evaluation and Risk Management under TSCA Section 6**

Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency

Public Webinar  
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# Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for Methylene Chloride
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

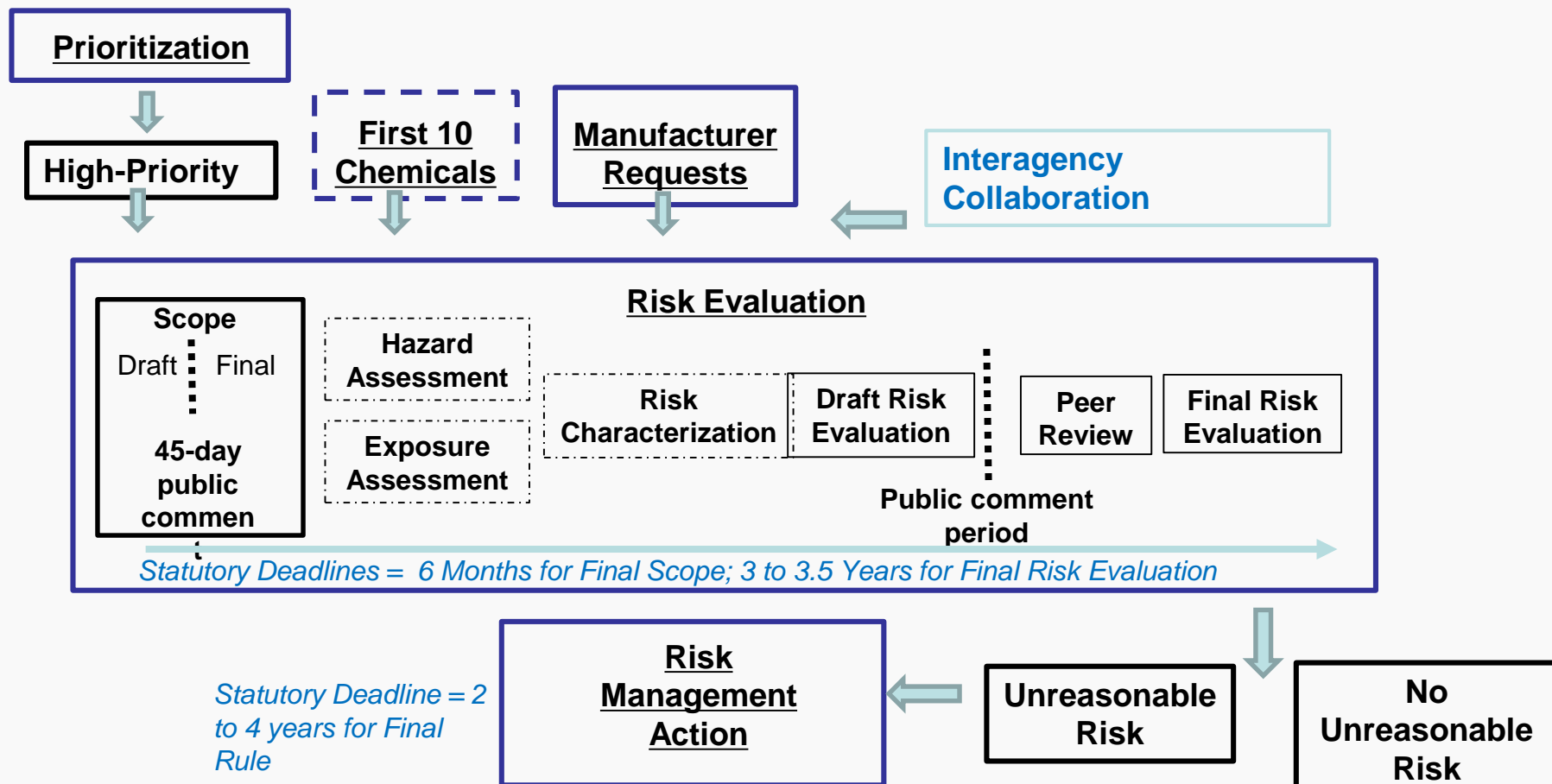


# Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 – 3.5 years



# Risk Evaluation Process and Timeline





# Overview of Risk Evaluation for Methylene Chloride

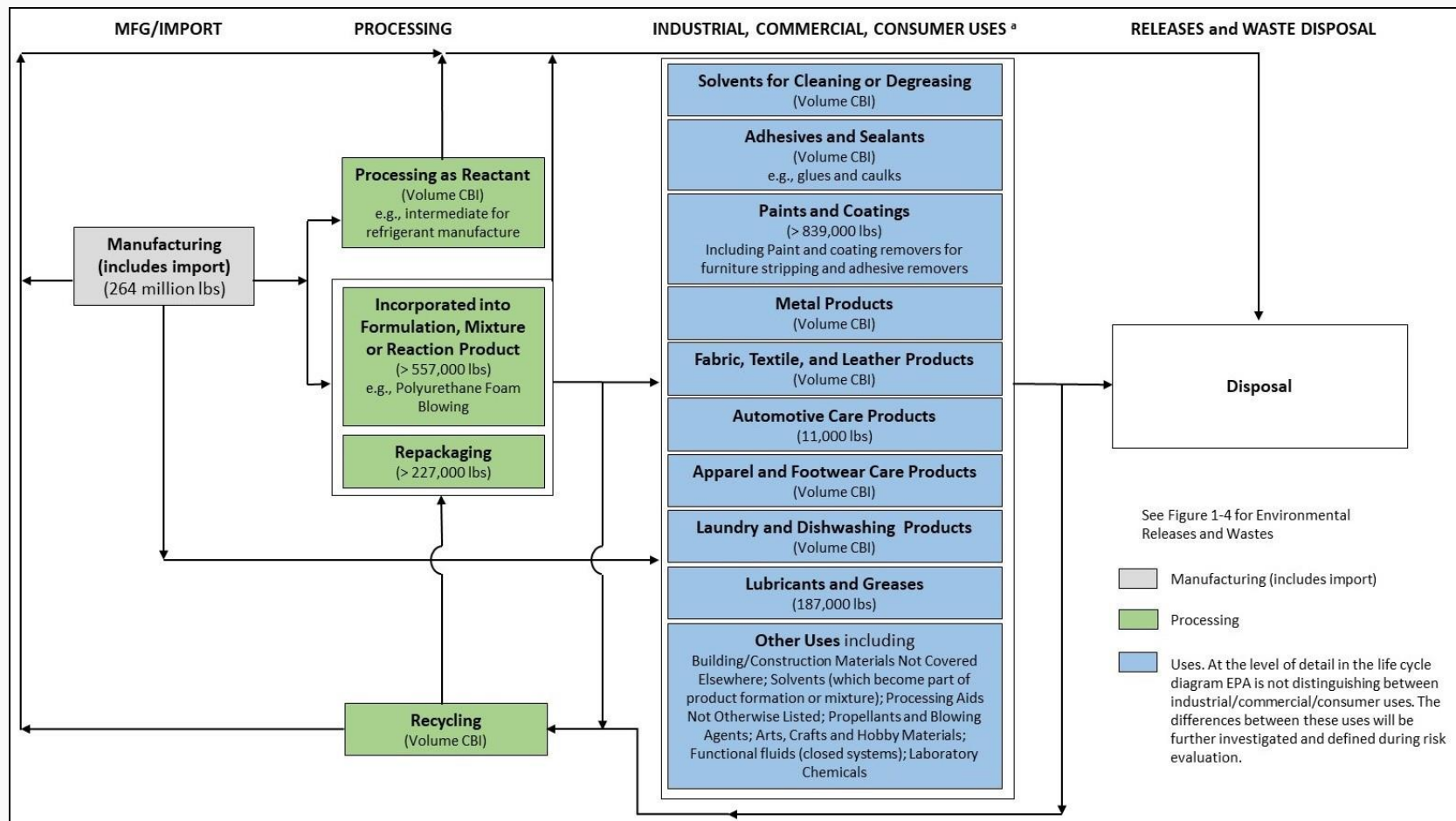
- Final risk evaluation published June 24, 2020
  - 53 conditions of use were evaluated
  - Final risk evaluation follows a series of risk evaluation activities
  - Methylene chloride (MC) draft risk evaluation: October 2019; MC problem formulation: June 2018; MC scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
  - 41 public comments received on the draft risk evaluation (comment period closed December 30, 2019)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (December 2019)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0437](https://www.regulations.gov/docket/EPA-HQ-OPPT-2019-0437), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0742](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0742), on [www.regulations.gov](https://www.regulations.gov)



# General Information on MC

- MC is a colorless liquid and a volatile organic chemical with a sweet odor resembling chloroform. It is both produced in and imported into the United States
- EPA identified conditions of use during various life cycle stages of MC, such as manufacturing (including import), processing, distribution in commerce, use (industrial, commercial, and consumer), and disposal
- MC has a wide range of uses, including as a solvent, propellant, processing aid, or functional fluid in the manufacturing of other chemicals
- A variety of consumer and commercial products use MC as a solvent including sealants, automotive products, and paint and coating removers
- The total aggregate production volume was ~264 million pounds between 2012 and 2015

# Methylene Chloride Life Cycle Diagram





# Determinations of No Unreasonable Risk

- EPA determined that MC does not present an unreasonable risk to the environment under the conditions of use
- EPA determined that the following six of the 53 conditions of use of MC do not present an unreasonable risk of injury to health or the environment:
  - Manufacturing (domestic manufacture)
  - Processing: as a reactant
  - Processing: recycling
  - Distribution in commerce
  - Industrial and commercial use as laboratory chemical
  - Disposal
- These no unreasonable risk determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)





# Unreasonable Risk Determinations

- EPA determined that 47 of the 53 conditions of use of MC present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
  - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute (central nervous system) and chronic (liver) inhalation and dermal exposure to MC
- EPA used central nervous system effects to identify unreasonable risks because relatively small increases in exposure can lead from central nervous system effects to more severe effects, including death



# Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Import
- Processing: incorporation into formulation, mixture, or reaction products
- Processing: repackaging
- Industrial and commercial use as solvent for batch vapor degreasing
- Industrial and commercial use as solvent for in-line vapor degreasing
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use in adhesives, sealants and caulks
- Industrial and commercial use in paints and coatings
- Industrial and commercial use in paint and coating removers
- Industrial and commercial use in adhesive and caulk removers
- Industrial and commercial use in metal aerosol degreasers
- Industrial and commercial use in metal non-aerosol degreasers
- Industrial and commercial use in finishing products for fabric, textiles and leather
- Industrial and commercial use in automotive care products (functional fluids for air conditioners)
- Industrial and commercial use in automotive care products (interior car care)
- Industrial and commercial use in automotive care products (degreasers)
- Industrial and commercial use in apparel and footwear care products
- Industrial and commercial use in spot removers for apparel and textiles



# Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk cont.

- Industrial and commercial use in liquid lubricants and greases
- Industrial and commercial use in spot removers for apparel and textiles
- Industrial and commercial use in liquid lubricants and greases
- Industrial and commercial use in spray lubricants and greases
- Industrial and commercial use in aerosol degreasers and cleaners
- Industrial and commercial use in non-aerosol degreasers and cleaners
- Industrial and commercial use in cold pipe insulations
- Industrial and commercial use as solvent that becomes part of a formulation or mixture
- Industrial and commercial use as a processing aid
- Industrial and commercial use as propellant and blowing agent
- Industrial and commercial use for electrical equipment, appliance, and component manufacturing
- Industrial and commercial use for plastic and rubber products manufacturing
- Industrial and commercial use in cellulose triacetate film production
- Industrial and commercial use as anti-spatter welding aerosol
- Industrial and commercial use for oil and gas drilling, extraction, and support activities
- Industrial and commercial use in toys, playground and sporting equipment
- Industrial and commercial use in lithographic printing plate cleaner
- Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner



# Consumer Uses that Present an Unreasonable Risk

- Consumer use as solvent in aerosol degreasers/cleaners
- Consumer use in adhesives and sealants
- Consumer use in brush cleaners for paints and coatings
- Consumer use in adhesive and caulk removers
- Consumer use in metal degreasers
- Consumer use in automotive care products (functional fluids for air conditioners)
- Consumer use in automotive care products (degreasers)
- Consumer use in lubricants and greases
- Consumer use in cold pipe insulation
- Consumer use in arts, crafts, and hobby materials glue
- Consumer use in an anti-spatter welding aerosol
- Consumer use in carbon removers and other brush cleaners



# Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of MC:
  - Central nervous system effects from acute inhalation
  - Liver effects from chronic inhalation
  - Cancer effects (liver and lung tumor) from chronic inhalation
- In some cases acute exposures to MC have led to fatalities
- Personal Protective Equipment (PPE):
  - The OSHA Methylene Chloride Standard sets a PEL of 25 ppm and requires air supplied respirators for occupational use.
  - Many conditions of use presented an unreasonable risk to workers even with use of respirators APF 25 or 50
  - No unreasonable risk to workers due to acute and chronic dermal exposures assuming use of gloves with PF of 5 or 10 in commercial settings and PF of 5 or 20 in industrial settings (exception: use of methylene chloride in spot removers for apparel and textiles)
  - EPA does not assume ONUs use PPE because they do not handle the chemical



# Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures of MC:
  - Central nervous system effects from acute inhalation and dermal exposure
- EPA does not assume dermal exposure to MC for bystanders
- EPA does not assume consumers or bystanders use PPE
- The unreasonable risk determinations were based on the high-end risk estimates for consumers and bystanders. Unreasonable risk was also presented for central tendency risk estimates for many COUs



# Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process
- Substantial increase in regulatory activities expected due to unreasonable risk findings across diverse conditions of use



# TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce.
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration.
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal.
- Require recordkeeping, monitoring or testing.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal by certain persons.
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase.





# TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users.
  - Can advise or recommend, but can regulate at the manufacturing, processing or distribution level in the supply chain for consumer use



# Examples of Regulatory Options

- Require manufacturers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain.
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL).
- Require monitoring of exposures in occupational settings.
- Require a hazard communication program to educate workers on label directions, warnings, etc.
- Prohibit or regulate manner of commercial disposal.



# Examples of Regulatory Options

- Set a concentration for a particular use, for example, product formulations cannot contain more than a certain percentage by weight
- Provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describe the health endpoints
- Prohibit manufacturing, processing and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls, ventilation requirements, and PPE at occupational sites
- Require manufacturers, processors, and distributors to maintain ordinary business records



## TSCA Section 6(c)

- In promulgating any rule under 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:
  - The effects and magnitude of exposure to human health,
  - The effects and magnitude of exposure to environment,
  - The benefits of the chemical for various uses,
  - The reasonably ascertainable economic consequences of the rule, including consideration of:
    - The likely effect on the national economy, small business, technological innovation, the environment, and public health;
    - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives; and
    - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives.



# Complex Consumer and Durable Goods—Section 6(c)(2)

- EPA shall exempt replacement parts for complex durable goods and complex consumer goods designed prior to publication of the risk management rule from section 6(a) unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation, to the general population or to an identified potentially exposed or susceptible subpopulation.
- “Complex consumer goods” means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace.
- “Complex durable goods” means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.



# Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs



# Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent



# Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective





# Coordination and Engagement

- In developing risk management approaches EPA:
  - Consults with stakeholders to learn about condition of use, existing engineering controls, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
  - Conducts site visits to obtain detailed information on existing practices in chemical manufacturing, processing, and use
  - Develops an extensive network among all stakeholders to ensure regulatory approaches are fully informed and based on current conditions



# Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
  - Methylene chloride: September 16
  - 1-Bromopropane: September 30
  - Other chemicals following their final risk evaluations
- Consultations seeking targeted feedback, with:
  - States and local governments
  - Tribes
  - Small businesses
  - Environmental justice organizations and communities



## Additional Information

- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- Methylene chloride: Ingrid Feustel ([Feustel.ingrid@epa.gov](mailto:Feustel.ingrid@epa.gov), 202-564-3199)
- General risk management outreach: Douglas Parsons ([parsons.douglas@epa.gov](mailto:parsons.douglas@epa.gov), 202-564-0341)